



February 11, 2005

SENATE BILL No. 206

DIGEST OF SB 206 (Updated February 9, 2005 12:28 pm - DI 104)

Citations Affected: IC 25-26; noncode.

Synopsis: Home medical equipment services provider licensing. Requires a home medical equipment services provider to be licensed by the board of pharmacy. Authorizes the board to conduct inspections, issue licenses, discipline providers for violations, and adopt rules to: (1) specify the equipment to be regulated; (2) set standards for the licensure of services providers; (3) govern the safety and quality of services that are provided; (4) recognize certain accredited individuals for purposes of issuing a temporary license; and (5) set reasonable fees for the application, issuance, and renewal of a license.

Effective: July 1, 2005.

Dillon

January 4, 2005, read first time and referred to Committee on Health and Provider Services.

February 10, 2005, amended, reported favorably — Do Pass.

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SB 206—LS 7019/DI 110+



February 11, 2005

First Regular Session 114th General Assembly (2005)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2004 Regular Session of the General Assembly.

SENATE BILL No. 206

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

1 SECTION 1. IC 25-26-21 IS ADDED TO THE INDIANA CODE
2 AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE
3 JULY 1, 2005]:

4 **Chapter 21. Home Medical Equipment Services Providers**

5 **Sec. 1. As used in this chapter, "board" refers to the Indiana**
6 **board of pharmacy established by IC 25-26-13-3.**

7 **Sec. 2. As used in this chapter, "home medical equipment"**
8 **means technologically sophisticated medical devices that may be**
9 **used in a residence, including the following:**

- 10 (1) Oxygen and oxygen delivery systems.
11 (2) Ventilators.
12 (3) Respiratory disease management devices.
13 (4) Continuous positive airway pressure (CPAP) devices.
14 (5) Electronic and computerized wheelchairs and seating
15 systems.
16 (6) Apnea monitors.
17 (7) Transcutaneous electrical nerve stimulator (TENS) units.

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- (8) Low air loss cutaneous pressure management devices.
- (9) Sequential compression devices.
- (10) Feeding pumps.
- (11) Home phototherapy devices.
- (12) Infusion delivery devices.
- (13) Distribution of medical gases to end users for human consumption.
- (14) Hospital beds.
- (15) Nebulizers.
- (16) Other similar equipment determined by the board in rules adopted under section 7 of this chapter.

Sec. 3. As used in this chapter, "home medical equipment services" means the:

- (1) sale;
- (2) rental;
- (3) delivery;
- (4) installation;
- (5) maintenance or replacement; or
- (6) instruction in the use;

of medical equipment used by an individual that allows the individual to reside in a noninstitutional environment.

Sec. 4. As used in this chapter, "provider" means a person engaged in the business of providing home medical equipment services to an unrelated individual in the individual's residence.

Sec. 5. (a) This chapter does not apply to the following:

- (1) A home health agency (as defined in IC 16-27-1-2) that does not sell, lease, or rent home medical equipment.
- (2) A hospital licensed under IC 16-21-2 that:
 - (A) provides home medical equipment services only as an integral part of patient care; and
 - (B) does not provide home medical equipment services through a separate business entity.
- (3) A manufacturer or wholesale distributor that does not sell, lease, or rent home medical equipment directly to a consumer.
- (4) Except as provided under subsection (b), a practitioner (as defined in IC 25-1-9-2) who does not sell, lease, or rent home medical equipment.
- (5) A veterinarian licensed under IC 15-5-1.1.
- (6) A hospice program (as defined in IC 16-25-1.1-4) that does not sell, lease, or rent home medical equipment.
- (7) A health facility licensed under IC 16-28 that does not sell, lease, or rent home medical equipment.

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(8) A provider that:

(A) provides home medical equipment services with the scope of the licensed provider's professional practice;

(B) is otherwise licensed by the state; and

(C) receives annual continuing education that is documented by the provider or the licensing entity.

(9) An employee of a person licensed under this chapter.

(b) A pharmacist licensed in Indiana or a pharmacy that holds a permit issued under IC 25-26 that sells, leases, or rents home medical equipment:

(1) is not required to obtain a license under this chapter; and

(2) is otherwise subject to the:

(A) requirements of this chapter; and

(B) requirements established by the board by rule under this chapter.

Sec. 6. (a) A person seeking to provide home medical equipment services in Indiana shall apply to the board for a license in the manner prescribed by the board.

(b) A provider shall do the following:

(1) Comply with:

(A) federal and state law; and

(B) regulatory requirements;

for home medical equipment services.

(2) Maintain a physical facility and medical equipment inventory in Indiana.

(3) Purchase and maintain in an amount determined by the board:

(A) product liability insurance; and

(B) professional liability insurance;

and maintain proof of the insurance coverage.

(4) Establish procedures to ensure that an employee or a contractor of the provider who is engaged in the following home medical equipment activities receive annual continuing education:

(A) Delivery.

(B) Orientation of a patient in the use of home medical equipment.

(C) Reimbursement assistance.

(D) Maintenance.

(E) Repair.

(F) Cleaning and inventory control.

(G) Administration of home medical equipment services.

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The provider shall maintain documentation of the continuing education received by each employee or contractor.

(5) Maintain clinical records on a customer receiving home medical equipment services.

(6) Establish home medical equipment maintenance and personnel policies.

(7) Provide home medical equipment emergency maintenance services available twenty-four (24) hours a day.

(8) Comply with the rules adopted by the board under this chapter.

Sec. 7. (a) The board may adopt rules under IC 4-22-2 to do the following:

(1) Specify home medical equipment in addition to the home medical equipment set forth in section 2 of this chapter that is to be regulated under this chapter.

(2) Set standards for the licensure of providers.

(3) Govern the safety and quality of home medical equipment services that are provided to customers.

(4) Recognize accreditation organizations under section 9 of this chapter.

(5) Specify the amount of insurance coverage required under section 6(b)(3) of this chapter.

(6) Set reasonable fees for the application, issuance, and renewal of a license under this chapter and set other fees permitted under IC 25-1-8.

(b) The board may consult with individuals engaged in the home medical equipment services business to advise the board on the formulation of rules under subsection (a). The individuals may not be compensated or reimbursed for mileage by the board.

Sec. 8. (a) Except as provided in section 9 of this chapter, a provider must be licensed by the board before the provider may provide home medical equipment services. If a provider provides home medical equipment services from more than one (1) location in Indiana, the provider must obtain a license under this chapter for each location.

(b) An applicant shall submit the application to the board on a form adopted by the board. The nonrefundable application fee set by the board must be submitted with the application. The fee must be deposited in the state general fund.

(c) If the board determines that the applicant:

(1) meets the standards set forth by the board; and

(2) has satisfied the requirements under this chapter and the

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requirements established by the board by rule;
the board shall notify the applicant in writing that the license is being issued to the applicant. The license is effective on the applicant's receipt of the written notification.

(d) A license issued under this chapter is effective for not more than two (2) years, beginning on a date determined by the board. An entity that is licensed under this chapter shall display the license or a copy of the license on the licensed premises.

(e) The board may renew a license every two (2) years.

Sec. 9. (a) An applicant for a license under this chapter may submit documents that show the applicant's accreditation through a national organization recognized by the board.

(b) The board shall issue a temporary license to an applicant under subsection (a) when the board:

(1) receives a copy of a valid accreditation letter from a national organization that the board has recognized by rule under section 7(a)(4) of this chapter; and

(2) has conducted an inspection under section 10 of this chapter in which the inspector determines that the applicant meets the inspection requirements.

Sec. 10. (a) The board may inspect the operations and facilities of an applicant for a license under this chapter to determine whether to issue the applicant a license.

(b) The board may conduct random inspections at any time for the following reasons:

(1) To ensure the integrity and effectiveness of the licensing process.

(2) To investigate a consumer complaint or a complaint by a qualified source as identified by the board.

(3) To ensure continuing compliance with the licensing requirements under this chapter.

(c) The board shall provide the provider a report of the board's findings after the board completes an investigation under this section.

(d) A provider that disputes the report in subsection (c) may file an appeal under IC 4-21.5 with the board not later than thirty (30) days after receipt of the report. The board shall review the inspection report and, upon the provider's requests, conduct a new inspection.

(e) The board shall employ qualified inspectors to investigate complaints and conduct inspections. Investigators may review and audit records under an investigation or inspection during the

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inspected facility's normal business hours at the place of business of the provider being investigated.

(f) The board and the board's employees may not disclose confidential information obtained during an investigation except:

(1) during a disciplinary hearing held under section 11 of this chapter; or

(2) under a court order.

Sec. 11. The board may discipline the holder of a license under IC 25-1-9 after a hearing or for any of the following reasons:

(1) Violation of this chapter or violation of a rule established by the board.

(2) Violation of a board order.

(3) Failure to meet the standards set forth in section 6(b) of this chapter.

(4) The conviction or plea of guilty for a felony or misdemeanor that:

(A) involves fraud or deceit; or

(B) is directly related to providing home medical equipment services.

(5) Negligence or gross misconduct in providing home medical equipment services.

(6) The aid, assistance, or willful allowance of another person in violating a provision under this chapter or a rule adopted by the board.

(7) Failure to provide within sixty (60) days information in response to a written request from the board.

(8) The engagement in conduct that is likely to deceive, defraud, or harm the public.

(9) Denial, revocation, suspension, or restriction of a license in another state or jurisdiction to provide home medical equipment services for a reason other than the failure to renew the license.

(10) The receipt of a fee, commission, rebate, or other form of compensation for services not rendered.

(11) Knowingly making or filing false records, reports, or billings in the course of providing home medical equipment services, including false records, reports, or billings prepared for or submitted to state or federal agencies or departments.

(12) Failure to comply with federal rules issued under the federal Medicare program (42 U.S.C. 1395 et seq.) relating to operations, financial transactions, and general business practices of home medical equipment services providers.

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1 **Sec. 12. (a) A person engaging in the business of home medical**
 2 **equipment services who:**

3 **(1) is required to be licensed under this chapter; and**

4 **(2) knowingly provides home medical equipment services**
 5 **without a license issued under this chapter;**

6 **commits a Class A misdemeanor.**

7 **(b) Each day a violation continues constitutes a separate offense.**

8 **(c) The board may, in the name of the state and through the**
 9 **attorney general, apply in a court to enjoin a person from**
 10 **providing home medical equipment services in violation of this**
 11 **chapter.**

12 **SECTION 2. [EFFECTIVE JULY 1, 2005] (a) As used in this**
 13 **SECTION, "board" refers to the Indiana board of pharmacy**
 14 **established by IC 25-26-13-3.**

15 **(b) As used in this SECTION, "provider" has the meaning set**
 16 **forth in IC 25-26-21-4, as added by this act.**

17 **(c) A person engaged in providing home medical equipment**
 18 **services (as defined in IC 25-26-21-3, as added by this act) business**
 19 **on June 30, 2005, and through June 30, 2006, is subject to**
 20 **inspection by the board for compliance with the standards set forth**
 21 **in IC 25-26-21, as added by this act.**

22 **(d) If, on the initial inspection under subsection (c), a provider**
 23 **who is accredited by a national organization passes the inspection,**
 24 **the board shall issue the provider a license under IC 25-26-21, as**
 25 **added by this act. If, on the initial inspection under subsection (c),**
 26 **a provider who is accredited by a national organization does not**
 27 **meet the inspection requirements, the board, after the adoption of**
 28 **rules under subsection (g) concerning the issuance of temporary**
 29 **licenses, shall issue the provider a temporary license for a period**
 30 **of twelve (12) months.**

31 **(e) When the board issues a temporary license under subsection**
 32 **(d), the board shall provide the provider in writing a list of the**
 33 **areas of noncompliance.**

34 **(f) After the twelve (12) month period described in subsection**
 35 **(d), the board shall conduct an inspection to determine whether the**
 36 **provider is in compliance with the standards set forth in**
 37 **IC 25-26-21, as added by this act. If the board determines that the**
 38 **provider meets the standards, the board shall issue the provider a**
 39 **license under IC 25-26-21, as added by this act. If the board**
 40 **determines that the provider is not in compliance, the board shall**
 41 **notify the provider in writing that the board is denying the**
 42 **provider a license.**

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- 1 (g) The board may adopt rules under IC 4-22-2 necessary to
2 implement this SECTION.
3 (h) This SECTION expires December 31, 2008.

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COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 206, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 2, line 36, delete "IC 25-1-11-2)" and insert "**IC 25-1-9-2)**".

Page 2, after line 42, begin a new line block indented and insert:

"(8) A provider that:

(A) provides home medical equipment services with the scope of the licensed provider's professional practice;

(B) is otherwise licensed by the state; and

(C) receives annual continuing education that is documented by the provider or the licensing entity.

(9) An employee of a person licensed under this chapter."

Page 3, line 1, after "pharmacy" insert "**that holds a permit issued under IC 25-26**".

Page 3, line 3, after "chapter;" insert "**and**".

Page 3, line 4, after "is" insert "**otherwise**".

Page 3, line 17, delete "on a site zoned for commercial use,".

Page 3, line 23, delete "personnel" and insert "**an employee or a contractor of the provider who is**".

Page 3, line 25, delete "education established by the board:" and insert "**education:**".

Page 3, between lines 33 and 34, begin a new line block indented and insert:

"The provider shall maintain documentation of the continuing education received by each employee or contractor."

Page 4, line 27, delete "may" and insert "**must be deposited in the state general fund**".

Page 4, delete lines 28 through 29.

Page 4, line 38, after "board." insert "**An entity that is licensed under this chapter shall display the license or a copy of the license on the licensed premises**".

Page 5, between lines 17 and 18, begin a new line block indented and insert:

"(3) To ensure continuing compliance with the licensing requirements under this chapter."

Page 5, line 18, delete "send" and insert "**provide**".

Page 5, line 22, after "appeal" insert "**under IC 4-21.5**".

Page 6, line 2, delete "dishonesty;" and insert "**fraud or deceit**";.

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Page 7, line 12, delete "the provider shall be issued" and insert "**the board, after the adoption of rules under subsection (g) concerning the issuance of temporary licenses, shall issue the provider**".

Page 7, line 26, after "(g)" insert "**The board may adopt rules under IC 4-22-2 necessary to implement this SECTION. (h)**".

and when so amended that said bill do pass.

(Reference is to SB 206 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 9, Nays 0.

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